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Psychological therapies for women who experience intimate partner violence (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

Psychological therapies for women who experience intimate partner violence

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of psychological interventions in comparison to usual care, no treatment, delayed provision of psychological interventions and minimal interventions (such as screening, information provision and referral to community services such as women shelters) for women who experience intimate partner violence (IPV).

BACKGROUND

Description of the condition

Intimate partner violence (IPV) is a prevalent issue that exists across all countries, cultures and all levels of society, with 15% to 71% of women globally reporting violence from an intimate partner at some stage in their lives (Garcia-Moreno 2006; Krug 2002). The World Health Organization (WHO) more recently estimated almost one third of women who have been in a relationship have experienced physical and/or sexual violence from an intimate partner (World Health Organization 2013a). The variation between countries is thought to relate to different gender attitudes and equity across countries as well as reinforcing factors for violence such as poverty (Elsberg 2014). An Australian study estimated a cost of $13.6 billion in Australian dollars during 2009-2010 to the community, mainly resulting from pain, suffering and premature mortality (Commonwealth of Australia 2009). Domestic violence is estimated to cost the UK £16 billion per year including costs related to criminal justice health care, social services, housing and losses in economic output (Walby 2009). Therefore, there are also wider economic societal implications to be considered, in addition to the very serious individual consequences of IPV.

This review adopts the WHO definition of IPV as "any behaviour

within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship" (Krug 2002). This includes acts of psychological abuse, such as intimidation and constant belittling, and controlling behaviour such as monitoring movements, isolation from family and friends and restricting access to financial resources, medical care, employment and education (Krug 2002). Compared to men, women experiencing IPV are more likely to suffer from repeated, severe violence from their intimate partners and are also more likely to be murdered by a current or former intimate partner (World Health Organization 2013a). For these reasons, this review will focus on women exposed to IPV, although it is acknowledged that IPV against men is also an important issue. Future research needs to be developed for men exposed to violence including interventions for bi-directional violence.

Recent studies have estimated IPV as the leading cause of death, disability and illness for women of childbearing age (Vos 2006). Thirty-eight per cent of all murdered women (in contrast to 6% of all murdered men) are killed by intimate partners (World Health Organization 2013a). Non-fatal injuries are also common in women exposed to IPV. One study from the USA estimates that 50% of all acute injuries in women result from IPV (Guth 2000). Abused women commonly suffer with chronic health problems (Black 2001), present very frequently to healthcare services and require a wide range of medical services (Black 2001). The largest physical health difference between abused and non-abused women concerns gynaecological problems, including chronic pelvic pain, sexually-transmitted diseases and vaginal bleeding (Black 2001). Other conditions affecting abused women include chronic pain such as back pain and headaches, neurological symptoms such as fainting and seizures (Black 2001; Diaz-Olavarrietta 1999), and gastrointestinal disorders such as irritable bowel disease (Coker 2000). Further, abused women are prescribed more analgesia than non-abused women (Lo Fo Wong 2007). IPV is also a significant risk to pregnant women and their unborn children. The WHO recently reported abused women to be more than twice as likely to have an abortion, and 16% more likely to have a low birth weight baby (World Health Organization 2013a). IPV is also associated with increased rates of miscarriage, premature birth and foetal injury (Pallitto 2013; Taft 2004).

The most prevalent mental health problems in women exposed to IPV are depression, anxiety, post-traumatic stress disorder (PTSD) and alcohol use disorders (Howard 2013; Rees 2011; Trevillion 2012; World Health Organization 2013a). Abused women are more than twice as likely to suffer with depression compared with non-abused women (Devries 2013). Abused women have also been found to be more likely to suffer from PTSD compared with non-abused women (Oram 2013), and more likely to develop dependency on alcohol and illicit substances (Oram 2013). Women exposed to IPV often also suffer from low self-esteem and hopelessness (Papadakaki 2009). These problems impact upon women's ability to parent their children (McCosker-Howard 2006). Given this high prevalence of mental health problems in women exposed to IPV, there is a potential for cognitive behavioural interventions to improve women's mental health.

Description of the intervention

For the purpose of this review, psychological therapy interventions include a wide range of interventions that target cognition, motivation and behaviour (see Cochrane Common Mental Disorders (CCMD) Group's psychological therapies list on the Cochrane website for definitions). These include (a) formal cognitive behavioural therapy (CBT) and trauma-focused CBT (TF-CBT), and CBT-based techniques; (b) third wave CBTs e.g. Acceptance and Commitment Therapy, mindfulness; (c) integrative therapies including motivational interviewing; and (d) behaviour therapies e.g. Eye Movement Desensitisation Reprocessing (EMDR), and relaxation techniques, many of which are based upon cognitive behavioural processes (Freeman 2005). We will also include (e) humanistic therapies e.g. supportive and non-directive therapies; (f) other psychologically-orientated interventions e.g. art therapy, meditation, narrative therapy; and (g) brief psychodynamic therapies. We will not including systemic therapies as this is mainly couple-based, which is contraindicated for women experiencing IPV by WHO guidelines (World Health Organization 2013b).

Cognitive behavioural processes (which form part of the therapies listed in a-e) can also be sub-classified into three major classes as follows (Dobson 2009): (1) cognitive re-structuring, which focuses on internal underlying beliefs and thoughts with the aim to challenge maladaptive thought patterns; (2) coping skills therapy which focuses on identification and alteration of cognitions and behaviours that may increase the impact of negative external events. This type of therapy is primarily used for problems that are external to the person, focusing on reducing the consequences of negative external events; (3) problem-solving therapies which combine cognitive re-structuring and coping skills therapy to change internal thought patterns and optimise responses to external negative events. These three classes each have a slightly different target for change, demonstrating the wide range of psychological interventions based upon cognitive behavioural principles (Dobson 2009).Other psychologically-orientated interventions aim to reduce stress and promote recovery from the trauma of the abuse.

The number of psychological intervention sessions in IPV intervention trials can vary greatly, from one to 20 sessions (Hegarty 2013; Kiely 2010). Examining the mental health literature and guidelines, low-intensity psychological interventions, for mild to moderate mental health symptoms is recommended at an intensity of at least five up to 12 sessions according to internationally recognised psychological guidelines (National Collaborating Centre Mental Health 2005; NICE 2009). High-intensity psychological interventions, for more severe symptoms, is recommended at an intensity of 16 to 20 sessions (NICE 2009). There is limited

evidence from IPV trials about the recommended length of treatment (World Health Organization 2013b). Similarly, there is wide variation across interventions with regard to who delivers the psychological intervention from formally trained mental healthcare workers to social work students (Kiely 2010), to trained healthcare workers and family doctors (Hegarty 2013).

How the intervention might work

In considering IPV interventions, it must first be recognised that women experiencing IPV often have little to no control over their partner's behaviour (Hegarty 2008). Furthermore, there may be limited insight into and labelling of the abuse. This is particularly relevant among women with poor self-esteem and social isolation, both of which are commonly associated with abusive relationships (Papadakaki 2009). Such individual- and relationship-level circumstances contribute to the difficult process of decision-making about accessing help and/or escaping the violence (O'Doherty 2016). Furthermore, factors in a person's community and the wider social and cultural milieu, and intersectionality of different factors - race, immigration status, surviving abuse add to the complexity of a woman's journey and need to be considered with respect to design and delivery of services for abused women (Chavis 2008). Therefore, decisions such as leaving an abusive relationship, disclosing abusive behaviour and uptake of safety behaviours are much more complex than they may appear.

In this complicated setting, we consider the role of psychological interventions and their potential for changing perceived support, cognitions, beliefs and behaviours. We will describe how CBT-based interventions, integrative therapies, humanistic therapies and other psychologically-orientated interventions might impact on a woman experiencing IPV. Firstly, cognitive behavioural interventions (e.g. formal CBT, CBT-based techniques,TF-CBT, third wave, behavioural) are based on the proposition that behaviours are often cognitively mediated (Butler 2006). Mental health and social problems may be influenced by underlying cognitions and resulting behaviours. Because cognitive activity may be monitored and altered, behaviours may be changed through cognitive changes (Dobson 2009). Therefore, addressing certain thinking patterns and beliefs may result in positive changes in symptoms, problems and behaviours that may reduce some of the negative consequences of IPV exposure (Butler 2006). It is important at this stage to recognise that women experiencing IPV often make significant efforts to minimise harm, and certain behaviours and cognitions (such as safety planning) have been associated with harm reduction (Tiwari 2005). These positive cognitions and behaviours provide a good example of important potential targets for psychological interventions. Further, third wave CBTs e.g. Acceptance and Commitment Therapy and Mindfulness CBT act on changing the function of psychological events and the individuals relationship to them through acceptance, being present and committed action (Hayes 2006). EMDR is thought to work for patients who have been traumatised by the fact that eye movements can reduce the intensity of disturbing thoughts, under certain conditions (Bisson 2013).

Integrative therapies e.g. motivational interviewing is one psychological intervention that may be useful in assisting women. Motivational interviewing is based on the Transtheoretical model (Miller 2002), which identifies five stages of change with various strategies identified to facilitate a shift from one stage to the next (Prochaska 1992). A number of authors have however challenged the application of the Transtheoretical model to partner abuse interventions (Chang 2005; Zink 2004), as women who are abused have minimal control over their partner's behaviour. Therefore, it is not immediately obvious what the target for change should be. For example, a woman might be cognitively and emotionally prepared to leave the relationship, but be constrained by an objective external barrier to change, and may take other actions such as safety behaviours (Chang 2005). Cluss and colleagues have proposed an alternative model, the Psychosocial Readiness Model, to describe the process of change for victims of partner abuse (Cluss 2006). The Psychosocial Readiness Model encompasses external as well as internal factors: awareness that the partner's behaviour is abuse, perceived support from others and self-efficacy/perceived power. Self-efficacy is the ability of women to believe that they can be successful when they take action (Benight 2004). It is a context-specific assessment of competence to perform a specific or range of tasks in a given domain (Bandura 1986). It has recently been proposed that this model could have application with regards to counselling women exposed to IPV using motivational interviewing (Hegarty 2008; Hegarty 2013; Saftlas 2014). Other integrative therapies e.g. interpersonal therapy and supportive counselling in which the therapist empathically engages the patient, helps the patient to feel understood and assists with organising their life, and solving life problems also has the potential to improve victim's mental health and ability to take action (de Mello 2005).

Thirdly, humanistic therapies e.g. supportive and non-directive therapy may be helpful for women exposed to IPV. For women who have decided that the abuse must end, but whose intentions are not translated into action due to perceived external barriers, then supportive interventions and problem-solving techniques may be helpful (Mynors-Wallis 2000). Problem-solving techniques help patients to efficiently identify problem areas, and generate and implement solutions. Mynors-Wallis has demonstrated the effectiveness of problem-solving therapy in a randomised controlled trial for depression in primary care settings, involving basic level psychological training of healthcare workers (Mynors-Wallis 2000). We know that depression is common in women exposed to IPV (World Health Organization 2013a), and we know from qualitative studies that abused women have identified primary care clinicians as a source of assistance from whom they would seek support (Feder 2006). Taken together, these findings support the likelihood of humanistic therapies being helpful for women exposed to IPV, delivered in an environment that is

likely to be acceptable to these women.

Finally, other psychologically-orientated interventions e.g. art therapy, music therapy, meditation, narrative therapy may be helpful conjuncts for women who have left the relationship to assist them in managing ongoing trauma symptoms.

This background supports the findings from emerging research as previously outlined, that psychological interventions may positively impact upon the mental health and well-being of women experiencing IPV (Hegarty 2013; Kiely 2010; Kubany 2004; Nelson 2012).

Why it is important to do this review

IPV is an internationally prevalent problem, with devastating, far-reaching and long-lasting individual and societal consequences. It is important to systematically gather and evaluate the existing evidence about interventions that may help women exposed to IPV.

The role of screening for IPV has been debated over recent years. The routine screening of women for IPV in health settings, in the absence of structured intervention, was shown in a Cochrane review to have limited impact upon health outcomes and re-exposure to violence (Taft 2013). A recent update of this review has not markedly altered the conclusions (O'Doherty 2015). This review did not recommend screening. However, a recent update of the 2004 review by United States Preventative Services Task Force, which only looked at those studies relevant to the USA, does recommend IPV screening within health services (Nelson 2012).

Beyond the screening debate, researchers have examined interventions that may be offered to women experiencing IPV. Recent WHO guidelines for health professionals recommend psychological interventions for women experiencing IPV (World Health Organization 2013b). In particular, it points to an emerging body of research suggesting that cognitive behavioural and motivational interviewing interventions may have a positive impact upon the mental health and well-being of women experiencing IPV (World Health Organization 2013b; Saftlas 2014). Nelson and colleagues found interventions such as counselling to reduce IPV exposure (Nelson 2012). More recently, Hegarty and colleagues delivered a brief counselling intervention based on motivational interviewing techniques, delivered by family doctors within healthcare settings, finding a reduction in depressive symptoms in women exposed to IPV (Hegarty 2013). Saflas and colleagues also found that a motivational interviewing intervention reduced depressive symptoms (Saftlas 2014). Kiely and colleagues conducted a randomised controlled trial of an integrated cognitive behavioural intervention delivered by psychologists and social workers, finding reduced exposure to IPV during pregnancy with improved pregnancy outcomes (Kiely 2010). Kubany and colleagues delivered a cognitive behavioural intervention in women exposed to IPV and found a reduction in post-traumatic stress symptoms (Kubany 2004). In the context of this important background evidence, this review will focus on the impact of psychological therapy interventions in women exposed to IPV.

Advocacy in the multifaceted form of legal, housing and financial advice, facilitated access to community resources such as shelters, emergency housing and psychological interventions and provision of safety planning advice or informal counselling is another intervention that may be offered to women (Rivas 2015). However evidence from a Cochrane review regarding the effect of advocacy for women exposed to IPV has been equivocal (Rivas 2015).

Further to this, the role of CBTs for male perpetrators has been examined in a Cochrane review, however conclusions were unable to be drawn due to a lack of relevant randomised controlled trials (Smedslund 2011). In addition, another Cochrane review examining the impact of educational and skills-based interventions for relationship violence among adolescents and young adults also found no impact upon episodes, attitudes or behaviours related to relationship violence (Fellmuth 2013). Further research is therefore required to investigate the effectiveness of alternative interventions.

The effectiveness of cognitive behavioural interventions in the treatment of depression, anxiety and PTSD in general populations has been well demonstrated in recent Cochrane systematic reviews (Bisson 2013; Butler 2006; Hunot 2007). Given the prevalence of these specific mental health problems among women experiencing IPV (World Health Organization 2013a), and guidance to offer women experiencing mental health problems and IPV standard treatment (World Health Organization 2013b), it is a reasonable extrapolation to examine the impact of psychological interventions on women experiencing IPV. Women exposed to IPV are often referred for psychological interventions, however the impact of these interventions remains uncertain. Before psychological interventions can be recommended, it is important to evaluate the helpfulness of these interventions in this population.

To our knowledge, the role of psychological interventions in women exposed to IPV has never been systematically assessed to the level of a Cochrane review (Feder 2009; Tirado-Munez 2010). This review seeks to address this important knowledge gap and provide practitioners and policy-makers with a further evidence base to guide effective responses to IPV.

OBJECTIVES

To assess the effects of psychological interventions in comparison to usual care, no treatment, delayed provision of psychological interventions and minimal interventions (such as screening, information provision and referral to community services such as women shelters) for women who experience intimate partner violence (IPV).

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and quasi-RCTs. Quasi-RCTs will be included as research in this area is still emerging. Cluster-RCTs and cross-over trials will also be eligible for inclusion.

Types of participants

Participant characteristics

We will include women aged 16 years and older. Where studies involve a subset of eligible participants, these studies will be included in the review if the study includes over 50% eligible participants who have been stratified, randomised and analysed separately.

Diagnosis

We will include women who self-report previous or current experience of IPV. This includes same-sex partners.

Co-morbidities

We will include women with co-existing mental health diagnoses and/or substance abuse issues.

Setting

We will include women recruited via healthcare and community settings. Healthcare settings here are taken to include general practice, antenatal and postnatal services, hospital emergency services, gynaecology services, sexual health clinics, mental health services, community health centres and drug and alcohol services. Community settings will include intimate partner violence organisations, justice settings and women refuge facilities.

Types of interventions

Experimental Intervention

The experimental intervention consists of psychological interventions, which are taken here to include a wide range of interventions that target cognition, motivation and behaviour. These include:

1. formal cognitive behavioural therapies (CBTs) and trauma-focused CBT (TF-CBT), and CBT-based techniques;
2. third wave CBTs e.g. Acceptance and Commitment Therapy, mindfulness;
3. integrative therapies including motivational interviewing;
4. behaviour therapies e.g. Eye Movement Desensitisation Reprocessing (EMDR), relaxation techniques, many of which are based upon cognitive behavioural processes (Freeman 2005);
5. humanistic therapies e.g. supportive and non-directive therapy; and
6. other psychologically-orientated interventions e.g. art therapy, meditation, narrative therapy.

We will include studies where interventions involved more than one session, where each session consists of at least 30 minutes. For all interventions, studies of any duration or frequency of treatment will be included, so long as treatment meets the above stated criteria.

Given the lack of standardised definitions for the training requirements, we have not applied any restrictions to the minimum training requirements for psychological therapy delivery as this would be an arbitrary restriction. Training for the delivery of these interventions will be liberal, and will include healthcare workers and lay people who have received training.There is a current lack of consensus regarding consistent minimum requirements for formal psychological therapy training. Using CBT as an example, the Beck Institute specifies important components of CBT in the Cognitive Therapy Scale, but does not specify the minimum training required to achieve such competencies (Young 1980). The British Psychological Society compiled a list of core competencies required for CBT delivery in recognition of the disparities between health professions with regards to CBT training, however the minimum training to achieve these competencies similarly was not specified (Roth 2007). Rakovshik and McManus attempted to review the effectiveness of CBT training, however they were unable to generate definitive conclusions regarding the relationship between CBT training and therapist competence (Rakovshik 2010). Furthermore, they were also unable to find a standardised definition of therapist competence, nor were they able to find a standardised method to measure such competence (Rakovshik 2010).

For all interventions, mode of intervention delivery will include face-to-face, telephone and computer-based delivery. Face-to-face and telephone interventions will be delivered by either healthcare workers or lay people with specific training in psychological techniques. Computer-based delivery may be developed by healthcare workers or by lay people, including intimate partner violence organisations. Both individual and group delivery of the intervention will be included.

Comparator intervention

Comparator interventions will consist of usual care, no treatment, delayed provision of psychological interventions (also referred to as waiting-list conditions) and minimal interventions such as screening, information provision and referral to community services such as women shelters.

Special circumstances

We will include studies where psychological interventions were delivered as an adjunct to advocacy or screening for intimate partner violence (IPV), where the control group received advocacy or screening without psychological interventions.

If we cannot assess these studies from available information, for example subgroup analyses data, this information will be assessed by contacting first/corresponding authors of relevant studies to obtain potentially relevant information.

Types of outcome measures

Studies that meet the above inclusion criteria will be included regardless of whether they report on the following outcomes.

Primary outcomes

1. Depression with outcome measures including the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff 1977), the Patient Health Questionnaire (PHQ) (Spitzer 1999), Beck Depression Inventory (BDI) (Beck 1961), Hospital Anxiety and Depression Scale (HADS) (Bjelland 2002) and Hamilton Depression Rating Scale (HAM-D) (Hamilton 1960).
2. Self-efficacy with outcome measures including the General Self-Efficacy Scale (GSE) (Schwarzer 1995).
3. Drop-outs from treatment.

NB. Depression and self-efficacy may be positively or negatively affected by interventions, and as such may both be regarded as either efficacy or adverse outcomes.

Secondary outcomes

1. Mental health with outcome measures including the Short Form 12-item survey (SF12) (Ware 1996).
2. Anxiety with outcome measures including the Patient Health Questionnaire (PHQ) (Spitzer 1999), Generalised Anxiety Disorder seven-item (GAD-7) (Kertz 2013; Spitzer 2006), Beck Anxiety Inventory (BAI) (Beck 1988) and Hospital Anxiety and Depression Scale (HADS) (Bjelland 2002).
3. Post-traumatic stress disorder with outcome measures including the PTSD checklist (PCL) (Blanchard 1996; Weathers 1991) and Short Screening Scale for DSM-IV Posttraumatic Stress Disorder (Breslau 1999).
4. Quality of life with outcome measures including the WHO Quality of Life scale - abbreviated version (WHOQOL-BREF) (Skevington 2004) and EuroQol-5 dimension (EQ-5D) (Brooks 1996).
5. Re-exposure to IPV including physical, sexual and psychological abuse with outcome measures including the Composite Abuse Scale (CAS) (Hegarty 2005), Revised Conflict Tactics Scale (CTS2) (Straus 1996) and Women's Experience with Battering (WEB) (Smith 1995).
6. Safety planning and/or safety behaviour and self-care activities with outcome measures including the Safety Behaviour Checklist (McFarlane 2004).
7. Use of healthcare and IPV services with outcome measures as defined in the individual studies, since we expect these to be study-specific as healthcare and IPV services vary greatly between different settings and countries.
8. Social support with outcome measures including the Oslo 3 Social Support Scale (OSS3) (Dalgard 1996), Interpersonal Support Evaluation List (ISEL) (Cohen 1983) and Inventory of Socially Supportive Behaviours (ISSB) (Barrera 1981).

Timing of outcome assessment

We will include all time frames, however it is acknowledged that shorter-term outcomes for re-exposure to IPV and quality of life may not see any effect. Short-term time frames will be classified as zero to six months, medium-term time frames will be classified as greater than six months to 12 months, and long-term time will be classified as periods greater than 12 months. The primary time frame will be medium-term time frames.

Hierarchy of outcome measures

In the case that more than one outcome measure is used to measure single outcomes in the included studies, in selecting a set of data for inclusion in meta-analysis, we will give preference to outcome measures according to the order in which they are listed above.

Search methods for identification of studies

The Cochrane, Common Mental Disorders Controlled Trials Register (CCMDCTR)

The Cochrane Common Mental Disorders Group (CCMD) maintain two clinical trials registers at their editorial base in York, UK, a references register and a studies-based register. The CCDMDCTR-References Register contains over 40,000 reports of randomised controlled treatment trials for common mental disorders (depression, anxiety, eating disorders, self-harm). Approximately 50% of these reports have been tagged to individual, coded trials. The coded trials are held in the CCMDCTR-Studies Register and records are linked between the two registers through the use of unique study ID tags. Coding of trials is based on the EU-Psi coding manual.

Reports of trials for inclusion in the Group's registers are collated from routine, generic searches of MEDLINE (1950-), Embase (1974-) and PsycINFO (1967-); quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) and review specific searches of additional databases. Reports of trials are also sourced from international trials registers c/o the World

Health Organization's trials portal (ICTRP), ClinicalTrials.gov, drug companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses.

Details of CCMD's core search strategies (used to identify RCTs) can be found on the Group's website with an example of the core MEDLINE search displayed in Appendix 1.

Electronic searches

We will search the group's specialised register, the CCMDCTR using the following strategies.

1. **CCMDCTR-Studies Register**

We will search the studies register using controlled vocabulary terms.

Comorbid healthcare condition = *(domestic violence or rape or sexual abuse or spousal abuse)*

2. **CCMDCTR-References Register**

We will search the references register using a more sensitive set of free-text terms to identify additional untagged/uncoded reports of RCTs:

Free-text = *(((home* or domestic* or spous* or partner* or women or woman or mother*) NEAR (abus* or violen*)) or "battered women" or (violen* NEAR (date or dating)) or rape or ((sex* NEAR abuse*) not child*:ti))*

3. We will conduct complementary searches on the following bibliographic databases using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource:

1. Ovid MEDLINE (1950 to present) - search strategy listed in Appendix 2
2. Ovid Embase (1980 to present)
3. Ebsco CINAHL (1982 to present)
4. Ovid PsycINFO (1806 to present)
5. Cochrane Central Register of Controlled Trials (CENTRAL) (all years)
6. Database of Abstracts of Reviews for Effectiveness (DARE) (all years)
7. Web of Science Social Science Citation Index (1900 to present)
8. Proquest Published International Literature on Traumatic Stress (PILOTS) (1871 to present)

We will apply no restrictions on date, language or publication status to the searches.

4. We will search the international trial registries via the World Health Organization's trials portal (ICTRP) and ClinicalTrials.gov to identify unpublished or ongoing studies.

Searching other resources

Grey literature

We will search sources of grey literature including dissertations and theses, clinical guidelines and reports from regulatory agencies in a non-systematic manner (where appropriate) including:

1. World Health Organization;
2. Domestic Violence Data Sources.

Reference lists

We will check the reference lists of all included studies and relevant systematic reviews to identify additional studies missed from the original electronic searches (for example, unpublished or in-press citations). We will also conduct a forward citation search on the Web of Science.

Correspondence

We will contact trialists and subject experts for information on unpublished or ongoing studies or to request additional trial data.

Data collection and analysis

Selection of studies

Two review authors (MT and JT) will independently assess the titles and abstracts of articles identified through the literature search against the inclusion criteria. Abstracts will be coded as 'retrieve' (eligible or potentially eligible or unclear) or 'do not retrieve'. In the event of disagreements about abstract inclusion, the full article will be assessed by both review authors and then discussed. If agreement cannot be reached by discussion, a third review author (LOD) will be consulted as mediator. Final decisions will be made by consensus.

Full-text articles for selected abstracts will then be retrieved, and each article will be assessed independently against the inclusion criteria by two review authors (MT and LOD). Studies will either be identified for inclusion, or identified for exclusion. We will contact study authors as required, to decide whether the inclusion criteria are met. We will record reasons for excluding ineligible studies. As with earlier stages of the study selection process, in the event of disagreements that cannot be resolved by discussion, a third author (KH) will be consulted as mediator. Final decisions will be made by consensus.

We will identify and exclude duplicate records and we will collate multiple reports that relate to the same study so that each study rather than each report is the unit of interest in the review.

We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Moher 2009) and 'Characteristics of excluded studies' table.

Data extraction and management

We will use a data collection form to extract study characteristics and outcome data which has been piloted on at least one study in the review. Two pairs of review authors (MT and LOD, GG and JT) will extract study characteristics and outcome data from included studies.

We will extract the following study characteristics.

1. Methods: brief description of study design and randomisation method, total duration of study and date and location of study.
2. Participants: total number of participants, baseline characteristics including gender and age range, study setting, study's inclusion criteria and exclusion criteria, number of eligible people recruited and assigned, numbers dropped out and numbers analysed.
3. Interventions: number of intervention groups, type of psychological intervention, mode of delivery, frequency and duration of delivery, level of mental health training of person delivering the intervention and the relevant comparator intervention characteristics.
4. Outcomes: primary and secondary outcomes, outcome measures used and timing of outcome measurement.
5. Notes: funding for trial, and notable conflicts of interest of trial authors.

We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We will resolve disagreements by consensus or by involving a mediator (KH). One review author (JT) will transfer data into the Review Manager (Revman 2014) file. We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (KH) will spot-check study characteristics for accuracy against the trial report.

Main comparisons

Psychological interventions versus usual care/waiting list/minimal interventions.

We will stratify the results by type of therapy (categories 1-6 in Types of interventions) should data allow.

Assessment of risk of bias in included studies

Individually-randomised trials

Two pairs of review authors (MT and LOD, GG and JT) will independently assess risk of bias for each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). Each review author will rate the included studies for each of the domains listed below with ratings of 'high risk of bias', 'low risk of bias' or 'unclear risk of bias' and provide the reason supporting their judgement. We will resolve any disagreements by contacting the study author as required, then by discussion. In the event of disagreements that cannot be resolved by discussion, a third review author (KH) will be consulted as mediator.

For individually-randomised trials, we will address the following domains to assess risk of bias.

1. Random sequence generation.
2. Allocation concealment.
3. Blinding of participants and personnel.
4. Blinding of outcome assessment.
5. Incomplete outcome data.
6. Selective outcome reporting.
7. Other bias - consistent with our associated reviews on advocacy and screening in IPV (Rivas 2015; Taft 2013), we will also assess for protection against contamination (whether measures were taken to prevent or minimise the possibility that women in the control arm might receive part, or all of the intervention, were described sufficiently to allow assessment of possible contamination between groups).

We will also assess the following.

1. Therapist qualifications.
2. Treatment fidelity (whether the therapy was measured against a manual or scale).
3. Researcher allegiance/conflict of interest (whether the researcher has a vested interest in the provided therapies).
4. Therapist allegiance/conflict of interest (whether the therapist has a vested interest in the provided therapies).

We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient-reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

Cluster-randomised trials

We will assess the risk of bias for cluster-randomised trials as outlined above for individually-randomised trials. In addition, we will address the following domains specific to cluster-randomised trials in accordance with Section 16.3.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b).

1. Identification and recruitment bias.
2. Baseline imbalance between randomised groups.
3. Loss of clusters.
4. Analysis does not use appropriate analytical methods that take into account the clustering.
5. Assess the possible differences between the intervention effects estimated with cluster- and/or individually-randomised

trials, for example contamination in individually-randomised trials, different randomisation units (such as, general practice versus community) and sample size of clusters in cluster-randomised trials.

Cross-over trials

We will first assess cross-over trials for their suitability in evaluating the psychological therapy intervention in women experiencing intimate partner abuse using the criteria described Section 16.4.2 of the *Cochrane Handbook for Systematic Reviews of intervention*. If the design is appropriate, in addition to the criteria outlined for individual-randomised trials and cluster-randomised trials (if the unit of allocation is a cluster e.g. stepped wedge cluster-randomised trial), we will address domains specific to cross-over trials as outlined in Section 16.4.3 of the *Cochrane Handbook for Systematic Reviews of intervention* (Higgins 2011b):

1. whether there is a carry-over treatment effect from one period to the next;
2. whether only first period data are available;
3. incorrect analysis is performed;
4. comparability of results with those from parallel-group trials;
5. drop-out of participants after the first treatment;
6. number of treatments or periods used unclear.

Measures of treatment effect

Dichotomous data

Counts and percentages by trial arm are required for each study that reports dichotomous outcomes. Using the summary data, we will calculate the pooled odds ratio (OR) and 95% confidence interval (CI) across the trials for each outcome. In studies where data required to calculate the OR are neither available nor obtainable from study authors, we will provide the findings as published by the study authors.

Continuous data

Means and standard deviations by trial arm are required for studies that report continuous outcomes. We will calculate the mean difference (MD) when the pooled trials use the same scale to measure the outcome of interest. We will calculate the standardised mean difference (SMD), where the absolute mean difference is divided by the pooled standard deviation, when the outcome is measured using different measurement scales. Data will be presented as a scale with a consistent direction of effect. Where means and standard deviations are not available or obtainable from the authors, we will provide the findings as published by the study authors. Continuous outcome data that do not have a normal distribution and are reported as medians and interquartile ranges in the papers will be described in the review using a narrative approach.

Unit of analysis issues

Cluster-randomised trials

Statistical methods for cluster-randomised trials that allow for the effect of clustering are described in Section 16.3.3 of the *Cochrane Handbook for Systematic Reviews* (Higgins 2011b). If studies have not accounted for the effects of clustering in the analysis, we will use an approximate analyses as described in Section 16.3.6 of the *Cochrane Handbook for Systematic Reviews* (Higgins 2011b), which in addition to summary measures nominated for continuous and binary outcomes above, requires an estimate of the intra-class correlation coefficient of the outcome (ICC) and average cluster size. The ICC quantifies the proportion of the total variability of the outcome attributable to the variability between clusters (Donner 2000). When available, we will extract estimates of the ICC directly from the published papers. If not reported, we will contact the study authors in an attempt to obtain such data; otherwise we will obtain estimates of the ICC from external sources. We will conduct a sensitivity analysis using a range of plausible values for the ICC when the estimates of ICC have not been obtained from the trial data.

Cross-over trials

Statistical methods described in Sections 16.4.5 and 16.4.6 of the *Cochrane Handbook for Systematic Reviews of intervention* (Higgins 2011b) will be used to incorporate cross-over trials into the meta-analysis. We will conduct sensitivity analyses when missing data, such as the standard error of the estimated treatment effect or within-individual correlation coefficient, have been imputed for the meta-analyses. For cross-over trials where the unit of allocation is the cluster, we will use appropriate statistical methods, as outlined for cluster-randomised trials, to account for the clustering in the data. For the meta-analysis, we will analyse parallel group and cross-over trials separately and combine them (Section 16.4.7 of the *Cochrane Handbook for Systematic Reviews of intervention* (Higgins 2011b)).

Studies with multiple treatment groups

Where multiple trial arms are reported in a single trial, we will include only the relevant arms. Statistical methods for studies with multiple intervention groups to be used in this review are described in Section 16.5.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). We will examine studies to see whether they have accounted for the effects of multiple interventions in their trials. If meta-analysis is able to be conducted, we

will combine all relevant control groups into a single group, and combine all relevant intervention groups into a single group.

Dealing with missing data

We will contact study authors in an attempt to verify key study characteristics and obtain missing numerical outcome data where possible. We will document all correspondence with study authors, and we will report which study authors responded in the full review.

It will not be possible to use analytical methods that handle missing data because only summary data will be collected from the studies and individual level data will not be sourced from the authors (Egger 2001). We will address the potential impact of missing outcome data in the assessment of risk of bias described earlier. If appropriate, a sensitivity analysis will be performed to assess the impact of the missing information about the studies on the results of the systematic review as described in Sections 16.2.2 (dichotomous outcomes) and 16.2.3 (continuous outcomes) of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b).

Assessment of heterogeneity

Consistency of the results across studies will be assessed using graphical representations (Egger 1997) and will be quantified using the I^2 statistic (Deeks 2017), which measures the proportion of variation of the estimated treatment effect attributable to heterogeneity across studies included in the meta-analysis rather than sampling error. The observed value of I^2 will be interpreted using the guide given in Chapter 9.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017) and taking into consideration the size and direction of effects and the strength of evidence for heterogeneity using the P value from the Chi^2 test and the 95% confidence interval for I^2. As outlined in *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017), a rough guide to interpretation of I^2 is as follows: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity and 75% to 100% represents considerable heterogeneity. Where there is evidence for statistical heterogeneity, strategies as outlined in Chapter 9.5.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017) will be employed to identify potential sources of heterogeneity among the results of the studies. In particular, differences in the characteristics of the studies or other factors will be explored as possible explanations for heterogeneity in the results. Any differences identified will be summarised in the narrative summary.

Assessment of reporting biases

We will construct funnel plots if there are more than 10 studies, to investigate any association between effect size and study precision (which is closely related to sample size) (Egger 1997). Such an association could be due to publication or related biases, or due to systematic differences between small and large studies. If an association is identified, clinical diversity of the studies will be further examined as a possible explanation. If appropriate, we will also conduct sensitivity analysis to determine whether assumptions about the effect of the bias would impact the estimated treatment effect and the conclusions of the review.

Data synthesis

We will perform a meta-analysis if there are sufficient data and it is meaningful to pool the data across the studies, for instance if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense.

The decision whether to perform meta-analysis will be determined by the comparability of populations, denominators and interventions (clinical heterogeneity), the comparability of the duration of follow-up (methodological heterogeneity) and comparability of outcomes. A random-effects model will be used to analyse the data across the studies. If it is inappropriate to combine the data in a meta-analysis, the effect sizes with 95% CIs or standard errors of individual studies will be reported and summarised using a narrative approach.

Subgroup analysis and investigation of heterogeneity

We are aware of the limitations of subgroup analyses, however we remain interested in the following topics in relation to our primary outcomes. If sufficient numbers of studies are identified, we will perform subgroup analyses for the following.

1. Recruitment setting of participants: healthcare setting, community setting, shelter setting.
2. Type of intervention: CBT (including TF-CBT).
3. Intensity of intervention: two to five sessions, five or more sessions.
4. Person delivering the intervention: healthcare workers, non healthcare workers.

Recruitment setting has been identified for subgroup analysis as there may be differences in severity of IPV exposure between women recruited via health care as opposed to community settings or shelter settings. Recruitment setting may also influence the level of receptiveness to psychological intervention. Subgroup analyses regarding the type and intensity of interventions, as well as the background of the person delivering the intervention, have important practical implications for our review findings and recommendations.

We will use a simple approach described in Chapter 9.6.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017) to investigate whether there is a difference in the intervention effect between the subgroups. If there is a sufficient number of studies in the meta-analysis (at least 10), meta-regression techniques as described in Chapter 9.5.4 of the *Cochrane Handbook*

for Systematic Reviews of Interventions (Deeks 2017) will be used instead.

If a large degree of heterogeneity is identified, we will first check data for errors. If data are correct, we will conduct a sensitivity analysis by excluding certain studies from the existing meta-analysis to assess the influence of the studies on the degree of heterogeneity.

Sensitivity analysis

Primary analyses will be based on available data from all included studies relevant to the comparison of interest. We will perform sensitivity analyses to determine whether conclusions are robust to decisions made during the review process, such as quality of data, the inclusion/exclusion of studies from meta-analysis or approaches to analyses. These sensitivity analyses may include the following.

1. Study quality - allocation concealment will be used as a measure of study quality. If studies are rated 'low' risk of bias for allocation concealment then they are high quality; if 'unclear' or 'high' they are rated as low quality.
2. Differential dropout - we will exclude trials where dropouts are replaced without randomisation.
3. Impact of missing outcome data - we will exclude trials where missing data have been imputed.

Additional sensitivity analyses may be required if particular issues related to the studies under review arise.

'Summary of findings' table

We will prepare 'Summary of findings' tables to summarise key findings of this review. We will select up to seven of the most important outcomes (including adverse outcomes) and present standardised effect size estimates and 95% CIs, using the GRADE approach to assess the quality of the body evidence. We will use GRADEpro to create our 'Summary of findings' tables (GRADEpro 2008) and follow standard methods as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a) to prepare our 'Summary of findings' table. The following seven important outcomes (measured in the medium term) that will be included.

1. Depression with outcome measures including the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff 1977), the Patient Health Questionnaire (PHQ) (Spitzer 1999), Beck Depression Inventory (BDI) (Beck 1961), Hospital Anxiety and Depression Scale (HADS) (Bjelland 2002) and Hamilton Depression Rating Scale (HAM-D) (Hamilton 1960).
2. Self-efficacy with outcome measures including the General Self-Efficacy Scale (GSE) (Schwarzer 1995).
3. Dropouts from treatment.
4. Anxiety with outcome measures including the Patient Health Questionnaire (PHQ) (Spitzer 1999), Generalised Anxiety Disorder seven-item (GAD-7) (Kertz 2013, Spitzer 2006), Beck Anxiety Inventory (BAI) (Beck 1988) and Hospital Anxiety and Depression Scale (HADS) (Bjelland 2002).
5. Post-traumatic stress disorder with outcome measures including the PTSD checklist (PCL) (Blanchard 1996, Weathers 1991) and Short Screening Scale for DSM-IV Posttraumatic Stress Disorder (Breslau 1999).
6. Quality of life with outcome measures including the WHO Quality of Life scale - abbreviated version (WHOQOL-BREF) (Skevington 2004) and EuroQol-5 dimension (EQ-5D) (Brooks 1996).
7. Re-exposure to IPV including physical, sexual and psychological abuse with outcome measures including the Composite Abuse Scale (CAS) (Hegarty 2005), Revised Conflict Tactics Scale (CTS2) (Straus 1996) and Women's Experience with Battering (WEB) (Smith 1995).

'Summary of findings' tables will be created after we have entered data into RevMan (Revman 2014), written up our results and conducted the 'Risk of bias' assessment. However, the 'Summary of findings' table will be created before writing our discussion, abstract and conclusions, to allow the opportunity to consider the impact of the risk of bias in the studies contributing to each outcome upon the mean treatment effect and our confidence in these findings.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CCMD-CTR core MEDLINE search

CCMD's core search strategy used to inform the Group's specialised register: OVID Medline

A search alert based on condition + RCT filter only

1. *[MeSH Headings]:*

eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ or hyperphagia/ or bulimia/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/ or mood disorders/ or affective disorders, psychotic/ or bipolar disorder/ or cyclothymic disorder/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunctions, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or *Mental Disorders/

2. *[Title/ Author Keywords]:*

(eating disorder* or anorexia nervosa or bulimi* or binge eat* or (self adj (injur* or mutilat*)) or suicide* or suicidal or parasuicid* or mood disorder* or affective disorder* or bipolar i or bipolar ii or (bipolar and (affective or disorder*)) or mania or manic or cyclothymic* or depression or depressive or dysthymi* or neurotic or neurosis or adjustment disorder* or antidepress* or anxiety disorder* or agoraphobia or obsess* or compulsi* or panic or phobi* or ptsd or posttrauma* or post trauma* or combat or somatoform or somati# ation or medical* unexplained or body dysmorphi* or conversion disorder or hypochondria* or neurastheni* or hysteria or munchausen or chronic fatigue* or gambling or trichotillomania or vaginismus or anhedoni* or affective symptoms or mental disorder* or mental health).ti,kf.

3. *[RCT filter]:*

(controlled clinical trial.pt. or randomized controlled trial.pt. or (randomi#ed or randomi#ation).ab,ti. or randomly.ab. or (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or distribut* or expose* or fashion or number* or place* or recruit* or subsitut* or treat*)).ab. or placebo*.ab,ti. or drug therapy.fs. or trial.ab,ti. or groups.ab. or (control* adj3 (trial* or

study or studies)).ab,ti. or ((singl* or doubl* or tripl* or trebl*) adj3 (blind* or mask* or dummy*)).mp. or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or randomized controlled trial/ or pragmatic clinical trial/ or (quasi adj (experimental or random*)).ti,ab. or ((waitlist* or wait* list* or treatment as usual or TAU) adj3 (control or group)).ab.)
4. (1 and 2 and 3)
Records are screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs are tagged to the appropriate study record.
Similar search alerts are also conducted on OVID EMBASE and PsycINFO, using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource.

Appendix 2. MEDLINE search strategy

OVID MEDLINE will be searched using the following terms (1950 to present):
1. BATTERED WOMEN/
2. DOMESTIC VIOLENCE/
3. SPOUSE ABUSE/
4. (abuse$ adj3 wom#n).tw.
5. (abuse$ adj3 spous$).tw.
6. (abuse$ adj3 partner$).tw.
7. ((wife or wives) adj3 abuse$).tw.
8. ((wife or wives or wom#n) adj3 batter$).tw.
9. (partner$ adj3 violen$).tw.
10. (spous$ adj3 violen$).tw.
11. ((domestic* or home*) adj3 violen*).tw.
12. ((domestic* or home*) adj3 abuse*).tw.
13. (violen* adj3 (date or dating)).tw.
14. (date adj3 rape).tw.
15. (dating adj3 violen$).tw.
16. (acquaintance adj3 (rape or violen$)).tw.
17. ((relation* or interperson*) adj3 (abuse$ or violen$)).tw.
18. stalk*.tw.
19. ((domestic or marital or partner*1 or spous*) adj3 (rape or (sex* adj1 (abuse* or assault*)))).mp.
20. ((abuse* or violen*) adj3 (marital or marriage)).tw.
21. or/1-20
22. PSYCHOTHERAPY/ or PSYCHOTHERAPY, GROUP/
23. (psychotherapy or (psychological adj (therap* or intervention))).tw.
24. COGNITIVE THERAPY/
25. ((cogniti$ adj3 behavio$) or CBT).tw.
26. (cognitive resructur* or cognitive processing).tw.
27. (metacognitive or meta-cognitive).tw.
28. CBASP.tw.
29. BEHAVIOR THERAPY/
30. (behavio* adj3 (therap* or psychotherap* or intervention* or program* or training)).tw.
31. (behavio* activat*).tw.
32. (psychobehavio* or psycho-behavio*).tw.
33. COUNSELING/
34. counsel*.tw.
35. MOTIVATIONAL INTERVIEWING/
36. MOTIVATION/
37. (motivational adj3 (interview* or intervention* or therap* or psychotherap* or program* or training)).tw.
38. NONDIRECTIVE THERAPY/
39. (non-directive or nondirective).tw.
40. (analytic and (cogniti* or therap* or psychotherapy*)).tw.

41. (acceptance adj2 commitment).tw.
42. (compass* foc*).tw.
43. (dialectic* or DBT).tw.
44. diffusion.tw.
45. (mind train*).tw.
46. (mindful* or meditation or relaxation).tw.
47. (problem sol*).tw.
48. (rational emotive).tw.
49. (reality adj (therap* or psychotherap*)).tw.
50. BATTERED WOMEN/th or DOMESTIC VIOLENCE/pc or VIOLENCE/pc or SPOUSE ABUSE/th,pc
51. or/22-50
52. randomized controlled trial.pt.
53. controlled clinical trial.pt.
54. randomi#ed.ti,ab.
55. randomly.ab.
56. placebo.ab.
57. trial.ti,ab.
58. groups.ab.
59. (control$ adj3 (trial or study)).ab,ti.
60. ((singl$ or doubl$ or tripl$ or trebl$) adj3 (blind$ or mask$ or dummy)).mp.
61. ((waitlist* or (wait* adj2 list*)) and (control* or group)).ab.
62. ((usual care or care as usual) and (control* or group)).ab.
63. (treatment as usual or TAU).ab.
64. or/52-63
65. (21 and 51 and 64)

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